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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

NEVRO CORP.,

Plaintiff,

v.

FLATHEAD PARTNERS, LLC, f/k/a VENTURI GROUP LLC,

MAYO FOUNDATION FOR MEDICAL EDUCATION AND RESEARCH,

and MAYO CLINIC VENTURES, f/k/a MAYO MEDICAL VENTURES.

Defendants.

Case No.

COMPLAINT FOR

1. BREACH OF CONTRACT

2. BREACH OF CONTRACT FOR FAILURE TO ARBITRATE

DEMAND FOR JURY TRIAL

COMPLAINT

1. This action concerns a breakthrough medical technology developed in this District and elsewhere to relieve chronic pain without opioids or other medication. This technology is known as "paresthesia-free" spinal cord stimulation ("SCS"). SCS relieves pain using electrical pulses. For tens of thousands of patients suffering chronic pain, "paresthesia-free" SCS provides relief without the dangers of opioid addiction or other pharmaceutical side effects, and without undesired sensations.

2. Traditional SCS has an important shortcoming that has limited its effectiveness: paresthesia. Traditional SCS relies on technology that relieves pain but only by producing paresthesia, a sensation often described as tingling or pins-and-needles. The paresthesia masks the patient's area of pain. In theory, the patient feels the paresthesia and feels less pain. However, traditional SCS is not effective in a large portion of the population, the pain relief can be limited, and some patients experience uncomfortable side-effects like stimulations or even jolting sensations during movement, which can impair sleep or preclude driving a car while receiving therapy.

3. In 2009, Plaintiff Nevro Corp. ("Nevro") invented a new type of SCS that relieves pain without paresthesia. Nevro changed the SCS industry when it introduced its groundbreaking new therapy that defied conventional wisdom. In 2015, after clinical trials proved Nevro's "paresthesia-free" technology to be twice as effective as the incumbent technology, the FDA approved Nevro's SCS with a rare superiority label which allows Nevro to describe its SCS as superior to traditional SCS. Nevro has been awarded many patents recognizing and protecting its paresthesia-free technology.

4. The invention of Nevro's paresthesia-free technology follows years of trial-and-error experimentation, which led to many dead-ends. Over the years Nevro has collaborated with Stanford University, the University of California at Davis, and the Mayo Foundation for Medical Education and Research (the "Mayo Foundation"), among other research institutions. Nevro's collaboration with the Mayo Foundation, for example, tested whether neural "blocking" technology could be used to relieve chronic pain. That collaboration, however, showed that neural "blocking" technology was not going to be commercially suitable for Nevro due to unacceptable clinical side effects when applied to the spinal cord. Nevro investigated ways to overcome those side effects, but ultimately changed paths

and began pursuing other more promising therapy options. Nevro pursued those options through other collaborations, including with doctors at Stanford and Davis, where it did preclinical testing that supported the development of its differentiated paresthesia-free technology, which does not rely on neural "blocking" technology. In 2015, the Patent Trial and Appeal Board ("PTAB") issued a published decision distinguishing Nevro's paresthesia-free technology from neural "blocking" technology.

5. The present dispute arises out of Nevro's collaboration with Defendants. In 2006, Nevro[1] entered into an Amended and Restated License Agreement (the "Agreement") with Defendants Flathead Partners, LLC ("Flathead"), Mayo Foundation, and Mayo Clinical Ventures ("Mayo Ventures") (collectively, "Defendants").[2] The Agreement provides for, among other things, licensing rights to "know-how," and royalty payments therefor, and licensing rights to certain patents and patent applications, and royalty payments therefor. The Agreement gives Nevro the authority to prosecute any patents arising out of the Flathead-Nevro collaboration under the Agreement. Defendants have the right to consult with Nevro over the patent prosecution, but only Nevro has the right to prosecute these patents. Of particular relevance here, the Agreement provides that the parties shall arbitrate any disputes arising from the Agreement pursuant to an explicitly outlined framework and timeline. Importantly, the Agreement also provides for the availability of district court litigation as needed to obtain equitable relief, to prevent irreparable harm, and to compel specific performance of the arbitration terms.

6. Nevro has made all required royalty payments for "know how" license rights under the Agreement. To date, Nevro has not made, nor has it been required to make, royalty payments for patent license rights under the Agreement. Defendants have never sought to collect patent royalties, and have never initiated arbitration for patent royalties from Nevro.

7. For years the parties cooperated in prosecuting patent applications under the Agreement. For example, in 2014, Nevro successfully prosecuted U.S. Patent No. 8,798,754 (the

[1] Nevro was first incorporated in March 2006 under the name NBI Development, Inc. In June 2007, NBI Development, Inc., changed its name to Nevro Corp.

[2] A true and correct copy of the Agreement is attached as **Exhibit 1**.

"'754 patent") for "neural blocking therapy," a patent that is related to the '389 Knudson Application. Nevro and Defendants agreed that the '754 patent does not cover any Nevro commercial products, and thus Defendants have never sought patent royalties under the '754 patent. Notwithstanding that Nevro has not commercialized a product that is covered by the '754 patent, the '754 patent is of significant strategic value to Nevro, and thus Nevro diligently prosecuted the '754 patent and has invested in continuing to pay the maintenance fees for the '754 patent.

8. As directly relevant to the filing of this Complaint, Nevro has also diligently prosecuted U.S. Patent Application No. 16/286,389 (the "'389 Knudson Application"). First named inventor Mark Knudson [redacted]. The '389 Knudson Application is of significant strategic value to Nevro.

9. [redacted] after Nevro explained that the SENZA-RCT involved Nevro's "paresthesia-free" therapy, which the PTAB had acknowledged was different from the "blocking" technology claimed in the '389 Knudson Application. Significantly, Defendants have never collected patent royalties and have never initiated arbitration for patent royalties from Nevro.

10. In November 2021, after years of prosecution by Nevro, the Patent Examiner issued a Notice of Allowance for the then-pending claims of the '389 Knudson Application. A Notice of Allowance provides for the issuance of patent claims upon the payment of an Issue Fee and the fulfillment of other conditions.

11. In December 2021, Defendants made the stunning assertion that the allowed "blocking" claims of the '389 Knudson Application cover "paresthesia-free" therapy. Under Defendants' theory, the issuance of those claims would entitle them to patent royalties for Nevro's "paresthesia-free" products. This, however, is the same proposition that the PTAB rejected in 2015 and that [redacted]. Defendants' assertion reflects a desperate attempt to claim patent royalties to which they are not entitled by seeking the issuance of invalid claims at the Patent Office.

12. The timing of Defendants' assertion was strategic. If Nevro were to allow the claims to issue without disclosing Defendants' assertion to the Patent Office, Defendants would surely argue that Nevro accepted their interpretation of the claims, as opposed to the PTAB's interpretation. But more importantly, Defendants' view of the claims would render them invalid under 35 U.S.C. § 112 because the specification of the '389 Kundson Application does not disclose paresthesia-free therapy as the PTAB has already found. Thus, if Nevro paid the Issue Fee, that would have been a clear violation of Nevro's duty to disclose material information under 37 C.F.R. 1.56, and an act of inequitable conduct on the Patent Office.

13. Accordingly, Defendants' assertion required Nevro to disclose the invalidity issue to the Patent Examiner, which Nevro did in February 2022. In doing so, Nevro explained that "'block' … is a term of art that … does not cover paresthesia-free therapy. Applicant notes that in 2015, the PTAB stated: 'Knudson does not disclose a paresthesia-free therapy, either explicitly or inherently.'" Nevro amended the '389 Knudson claims to clarify the distinction between the blocking and paresthesia-free technologies. On the basis of Nevro's amendments and explanation, the Patent Examiner accepted Nevro's amended claims and allowed the claims. Thereafter, Nevro intended to pay the Issue Fee for the amended, valid claims to issue.

14. The shocking sequence of events leading directly to the filing of this Complaint began shortly after the Patent Examiner accepted Nevro's amendment and allowed the amended claims. On May 24, 2022, Defendants unilaterally revoked Nevro's power of attorney to prosecute the licensed patent applications; substituted new counsel into the '389 Knudson patent prosecution; withdrew Nevro's claim amendments, despite the fact that Nevro's claims had been allowed by the Patent Examiner; and filed claim amendments purporting to revert the '389 Knudson claims back to claims that Nevro believes are invalid under the requisite patent statutes. Nevro has informed Defendants and their attorneys of the grave invalidity concerns over the claims that the Defendants are now seeking to prosecute. Defendants' actions are a direct and clear breach of the Agreement.

15. Under the terms of the Agreement, Nevro notified Defendants that their actions were a breach of the Agreement. Defendants' actions in prosecuting the application will undoubtedly cause irreparable harm to Nevro, the sole exclusive licensee of the '389 Knudson Application. It is, however,

apparently Defendants' and their attorneys' intention to ram their claims through the patent process without clarifying amendments before they can be stopped by the arbitration process outlined in the Agreement.

16. In June 2022 Nevro attempted without success to convince Defendants to withdraw their amendments and return control of the patent prosecution to Nevro as required by the Agreement. On July 1, 2022, Nevro filed a notice of dispute under the arbitration clause of the Agreement and gave Defendants until July 15, 2022, to agree to standstill the patent prosecution to allow an orderly resolution of the parties' dispute in arbitration. Defendants responded to Nevro's request for a standstill by making additional filings before the Patent Examiner on July 7, 2022, and thus at least implicitly rejecting Nevro's request for a standstill until an arbitrator can decide the dispute over which party should be controlling prosecution of the '389 Knudson Application.

17. Nevro immediately filed this Complaint. Nevro's Complaint seeks specific performance of the arbitration terms of the Agreement to protect the arbitration by commanding Defendants to standstill the patent prosecution and to return control of the prosecution to Nevro. Nevro needs the power of this Court to protect its strategically valuable licensing rights, to protect the arbitration, and to secure its prosecution rights under the Agreement.

THE PARTIES

18. Plaintiff Nevro is a Delaware corporation with its principal place of business at 1800 Bridge Pkwy, Redwood City, CA 94065. Nevro researches, designs, and develops breakthrough technologies for spinal cord stimulation with the goal of helping more patients suffering from chronic pain to achieve lasting relief. Nevro's innovative products have earned a rare "superiority" label from the FDA, and have been called revolutionary, groundbreaking, and "amazing" by industry analysts. Nevro's innovations have catapulted the company to a near 20% share of the SCS market in only seven years, despite fierce competition from incumbents.

19. Flathead Partners LLC ("Flathead") is a limited liability company organized under the laws of the State of Minnesota in the United States, with its principal place of business in Minneapolis, Minnesota. [redacted]. Flathead was formerly known as the Venturi Group LLC or VGL. On information and belief, Flathead

was created for the purpose of making an investment in Nevro, and exists to manage the investment by collecting and distributing proceeds to investors.

20. Mayo Clinic Ventures (a/k/a Mayo Medical Ventures) ("Mayo Ventures") is a corporation organized under the laws of the State of Minnesota in the United States, with its principal place of business in Rochester, Minnesota. Mayo Foundation for Medical Education and Research ("Mayo Foundation") is a corporation organized under the laws of the State of Minnesota in the United States, with its principal place of business in Rochester, Minnesota. On information and belief, the Mayo Ventures is a subsidiary of the Mayo Foundation, or is owned by the same parent entity. On information and belief, Mayo Ventures exists to generate revenue by licensing and/or litigating technology developed by or in collaboration with the Mayo Foundation.

JURISDICTION AND VENUE

21. Nevro repeats and incorporates by reference all prior allegations of this Complaint as if fully set forth herein.

22. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 (federal question), 28 U.S.C. § 1332 (diversity), and 9 U.S.C. § 4 (compel arbitration). Defendants are citizens of different states than Nevro, and the amount in controversy exceeds $75,000. The value of the injunction sought by Nevro also exceeds $75,000. Nevro has paid Defendants [redacted], including for the right to prosecute the '389 Knudson Application and to enforce any resulting patent.

23. This Court has personal jurisdiction over each of the Defendants under Cal. Code Civ. Proc. § 410.10. This dispute arises out of a contract between Nevro (then called NBI) and Defendants signed in October 2006. At that time, Defendants knew that Nevro's principal place of business was being established in San Francisco, California and that Nevro's executive officers would be based there. At that time, Defendants had been working with Dr. Konstantinos Alataris and Bay City Capital, both residents of this District, to assist Dr. Alataris in forming Nevro. Over the years, Defendants have availed themselves of California with respect to the Agreement, and have extensively communicated and worked with Nevro in California. In addition, under the Agreement, Defendants received [redacted] in "know how" royalty payments from Nevro, and they were issued shares

of Nevro's common stock worth [redacted]. Defendants also regularly communicated with Nevro in California regarding prosecution of the '389 Knudson Application and related patent applications. Defendants further communicated with Nevro in California about Defendants' breach of the Agreement by revoking Nevro's right to control and direct prosecution of the '389 Knudson Application.

24. Venue is proper in this District under 28 U.S.C. § 1391(b). A substantial part of the events or omissions giving rise to the claim occurred in this District. Nevro's principal place of business is in this District, and its key witnesses live in this District. For over a decade, performance of the patent prosecution clause of the Agreement had been taking place in this District, with Nevro prosecuting the '389 Knudson Application and related patents. Research and development of technology disputed between the parties occurred in this District. Over the course of that time, Defendants repeatedly reached out to this District to coordinate with Nevro on prosecution activities. The parties had intended that performance of the Agreement occur, and continue to occur, in this District. And during that time, Defendants received [redacted] in compensation from Nevro in this District. After Defendants breached the Agreement by taking control of the patent prosecution, Nevro suffered and is suffering harm in this District. And Defendants communicated with Nevro in California about Defendants' breach of the Agreement.

ALLEGATIONS

25. Nevro repeats and incorporates by reference all prior allegations of this Complaint as if fully set forth herein.

26. Nevro researches, designs, develops, manufactures, and sells SCS systems to treat pain in patients. SCS therapy relieves pain by delivering electrical pulses to the spinal cord through electrodes that are implanted near the spinal cord. Nevro's pioneering SCS technology dramatically improves the quality of life of individuals suffering from chronic pain. Nevro's inventions were directed to a new type of SCS therapy relating to more effective pain treatment without generating paresthesia—a sensation usually described as tingling or pins and needles. Nevro has sought and obtained dozens of patents on that "paresthesia-free" therapy—patents that are solely owned by Nevro.

27. At the time of its development, Nevro's "paresthesia-free" therapy was a significant

advancement over the then-existing SCS therapy options, which worked by using paresthesia to mask a patient's chronic pain. Nevro's therapy treated pain without causing paresthesia, so that the patient neither felt pain nor paresthesia, and instead just felt relief. Nevro's SCS therapy uses unique programming of an implanted SCS system to deliver therapy to particular neural targets to provide pain relief without generating paresthesia. Nevro developed, tested, and patented a variety of technologies to provide "paresthesia-free" pain relief.

28. With its long history of providing paresthesia-based SCS therapy, the rest of the SCS industry was highly skeptical that Nevro's "paresthesia-free" SCS therapy would provide clinically effective pain relief. But to the industry's surprise, Nevro's paresthesia-free SCS therapy has been scientifically proven to provide significantly superior pain relief to a significantly larger population of patients. And it does so without the drawbacks of paresthesia-based SCS therapy.

29. Because Nevro's approach was fundamentally different from others in the market, the FDA put Nevro to a rigorous test. To obtain FDA approval, Nevro was required to prove both that its therapy is "paresthesia-free" and that its therapy was clinically effective even though it is "paresthesia-free." To obtain FDA approval, Nevro tested its 10,000 Hz "paresthesia-free" SCS therapy—its commercially marketed HF10® therapy—against a conventional paresthesia-based SCS system, in an FDA-monitored randomized, controlled, trial ("RCT"). The trial showed that Nevro's "paresthesia-free" SCS therapy is not only clinically effective without paresthesia, but also is nearly twice as effective as conventional paresthesia-based SCS therapy. As a result, when the FDA granted approval for Nevro's 10,000 Hz SCS therapy on May 8, 2015, it awarded Nevro's SCS therapy a rare "superiority" label, allowing Nevro to claim its SCS therapy is clinically superior to conventional paresthesia-based SCS therapy.

30. In addition to the FDA, Nevro's paresthesia-free therapy has been hailed by SCS industry scientists as a breakthrough, revolutionary, amazing, and unexpected technology. Industry analysts concluded that Nevro's breakthrough has almost single-handedly driven historic growth in the SCS industry. Nevro's revolutionary technology has allowed it to grow from 0% to approximately 20% share of the SCS market in only seven years—despite fierce competition from established incumbents. Nevro's life-changing products have helped relieve chronic pain in over 90,000 patients

worldwide.

A. History of the Parties' Relationship

31. Nevro was founded in 2006 by Dr. Konstantinos Alataris while he was working for venture capital firm Bay City Capital. At Bay City Capital, Dr. Alataris had been working on a project with Defendants [redacted]. [redacted], was developing a system for stimulating the vagus nerve to treat obesity by applying a 5,000 Hz stimulation signal to "block" the propagation of signals along that nerve. Importantly, the term "block" is a term of art, with a specific meaning in the scientific literature (*i.e.*, stopping all action potentials from propagating through a nerve as if the nerve were cut). Dr. Alataris and Defendants then sought to collaborate on another project.

32. On October 2, 2006, Nevro (then known as NBI Development, Inc.) entered into the Agreement with Defendants. The Agreement gave Nevro a license to use certain know-how from Defendants' work relating to neurostimulation and "block" therapy technology. At the time, it was thought that the "block" therapy technology, which prevented nerves from propagating action potentials past the block (*e.g.*, preventing transmission of hunger signals), could be used in other applications. Defendants' also agreed to perform certain testing and to consult on product development for Nevro. The Agreement gave Nevro a license to use any patents arising from that testing and development and, importantly, the right to control and direct prosecution of patent applications directed to that "block" therapy, which includes the '389 Knudson Application that is entitled "Neural blocking therapy." Defendants received significant ownership shares in Nevro, and rights to certain payments or royalties from Nevro.

33. Following its formation, Nevro researched "block" therapy technology and pursued its different applications. In general, "block" therapy consists of applying a high-amplitude electrical signal to a nerve, which stops neural electrical signals from traveling up the nerve from a limb to the brain, or down the nerve from the brain to a limb. While "block" therapy had been used on nerves (*e.g.*, the vagus nerve that transmits hunger signals to stop those signals from traveling to the brain) it had never been successfully used on the spinal cord. Nevro worked on trying to adapt this therapy to apply it to the spinal cord. That research, however, was not fruitful. Nevro was unable to get the

"block" therapy to work for Nevro's intended commercial application. As Nevro progressively tested the "block" on nerve populations closer to the spinal cord, these tests showed unacceptable side effects of "block" therapy, such as muscle spasms, loss of all feeling, and loss of motor skills. While Nevro investigated ways to mitigate or eliminate those side effects, at that time it was unable to find a commercially acceptable way to overcome those side effects and get it to work for a clinical application.

34. Nevro then pivoted away from "block" therapy technology, and began researching different therapy parameter options. Nevro, which was based in California at that time, started testing new therapy options at Stanford University, the University of California at Davis, and other institutions (testing not done by Defendants). The result of that testing was that Dr. Alataris and others at Nevro developed different SCS therapies applied to different neural populations to treat pain without producing paresthesia. Using Nevro's therapy, patients stopped feeling chronic pain signals but retained other sensory signals (*e.g.*, temperature and sharp pain) and motor control was unaffected. In 2009, Nevro filed applications for patents on that "paresthesia-free" therapy technology, and the PTO has issued Nevro many patents on this SCS therapy. Importantly, Nevro's "paresthesia-free" therapy was able to treat pain without using "block" therapy signals.

35. Defendants were well aware that the "block" therapy ran into problems for a commercial SCS application, that testing on it had stopped, and that Nevro began researching different SCS therapy options. Nevro informed Defendants of that fact, while Nevro continued to confer with Defendants about patent prosecution and other matters. Defendants knew that Nevro shifted to developing a "paresthesia-free" SCS therapy, obtained patents on that "paresthesia-free" therapy, and released products that could deliver that "paresthesia-free" therapy.

36. During prosecution of Nevro's "paresthesia-free" SCS patents, the PTO has considered whether the "block" therapy described in the '389 Knudson Application discloses the same "paresthesia-free" therapy that is disclosed in Nevro's patents. The PTO repeatedly has found that it does not. For example, the PTO has found that "Knudson[3] does not disclose a paresthesia-free therapy,

[3] Knudson, U.S. Patent Application Pub. No. US 2007/0073354 A1, pub. Mar. 29, 2007, is the parent application of the '389 Knudson Application, and contains the same specification.

either explicitly or inherently."[4] In all of these proceedings, Nevro has consistently distinguished the "block" therapy described in the '389 Knudson Application from Nevro's "paresthesia-free" SCS therapy, and the PTO has agreed with those distinctions.

37. During the development of Nevro's "paresthesia-free" SCS therapy and the prosecution of Nevro's patents, Nevro continued to confer with Defendants about the prosecution of the '389 Knudson Application (and its parent applications). Defendants were aware that Nevro's "paresthesia-free" therapy grew out of research separate from Defendants' research in "block" therapy technology. Defendants also were aware of Nevro's efforts to obtain patents on "paresthesia-free" therapy. Defendants also knew that Nevro filed for patents on "paresthesia-free" SCS therapy that did not name Defendants as inventors and that were solely owned by Nevro. Defendants further knew that the PTO had considered both Nevro's "paresthesia-free" therapy and Knudson's "block" therapy, and explicitly found that the two therapies are different. And Defendants also know that Nevro has successfully enforced and defended the validity of its "paresthesia-free" patents against three competitors that have infringed Nevro's "paresthesia-free" patents.

38. Nevro further secured the issuance of the '754 Patent in 2014 that was duly assigned to Defendant Flathead, related to use of neural-blocking for deep brain stimulation. Nevro also designed, developed, and submitted an Investigational Device Exemption (IDE) to the Bundesinstitut fur Arzneimittel und Medizinproduckete (BfArM) in Germany for a deep brain stimulation device, to study the safety and effectiveness of the device in clinical applications. Defendants had full awareness of that IDE.

39. When Nevro launched its Senza® SCS System that provides "paresthesia-free" therapy in the United States in 2015, and because Nevro had acquired some knowledge about clinical testing through its work with Defendants in the early days, Nevro began paying Defendants royalties for "know how" under the Agreement. The Agreement included two different royalty payment arrangements: The first specified that Nevro would pay a royalty payment of [redacted]

[4] A true and correct copy of Case No. IPR2015-01204, Decision Denying Institution of *Inter Partes* Review is attached as **Exhibit 2**. IPR2015-01204, Inst. Dec. at p. 10 (**Exhibit 2**) (footnote added).

for products developed using "know-how" learned from meetings with or testing done by Defendants. The second specified that Nevro would pay a royalty payment of [redacted] for products covered by a valid claim of a licensed patent. After Nevro launched its Senza® SCS system that could deliver HF10® therapy, Nevro paid Defendants [redacted] under the "know-how" rate. Over the applicable royalty term, Nevro paid Defendants [redacted]. Nevro, however, never paid any royalties under Defendants' patents because none of Defendants' patents covered Nevro's products. Defendants never objected to these payments and willingly accepted them [redacted].

B. Despite Nevro's Contractual Right to Control Prosecution of the '389 Knudson Application, Defendants Improperly Took Control to Change the Scope of the Claims

40. The '389 Knudson Application is entitled "Neural Blocking Therapy," and it claims priority back to U.S. Patent Application No. 11/235,947, filed in 2005. During the first 15 years of the Agreement, Nevro directed and controlled prosecution of the '389 Knudson Application and related patents in accordance with the Agreement's express grant of the control and authority to Nevro. Nevro conferred with Defendants about prosecution and obtained the related '754 Patent from those efforts. As the Agreement clearly provides:

> **8.01 Patent Filing, Prosecution, Maintenance and Enforcement. …**
>
> COMPANY [Nevro] shall have control and authority to direct prosecution of the Licensed Patents and Jointly Owned Patents, including the right to amend such patent applications and file new patent applications which shall be considered within the definition of Licensed Patents and/or Jointly Owned Patents, and FOUNDERS [Defendants] will be afforded the opportunity to advise and consult on all such filings and the prosecution.

41. On December 2, 2021, the Defendants notified Nevro in writing of a dispute over the scope of the then-pending claims of the '389 Knudson Application. Defendants asserted that the pending claims of the '389 Knudson Application covered "paresthesia-free" therapy, and that the specification of the '389 Knudson Application supported such claims under 35 U.S.C. § 112. This surprised Nevro because based on communications with Defendants in prior years, Nevro believed that Defendants were in agreement with Nevro that the scope of the claims and specification of the '389 Knudson Application were limited to "blocking" therapy. Nevro informed Defendants that the positions they were taking with regards to the scope of the claims and specification of the '389

Knudson Application directly conflicted with positions that Nevro has explicitly taken at the U.S. Patent Office and in district court litigation. Nevro also reminded Defendants that the positions they were taking directly conflicted with findings by the U.S. Patent Office, which explicitly found that the '389 Knudson Application did not disclose "paresthesia-free" therapy in 2015.

42. Defendants' assertion that the claims of the '389 Knudson Application could be interpreted as covering "paresthesia-free" SCS therapy—concepts not described in the '389 Knudson Application and not invented until years later—signified that the then-pending claims of the '389 Knudson Application required clarification and amendment under at least 35 U.S.C. § 112 and 37 C.F.R. 1.56. Nevro extensively discussed this issue with Defendants between December 2021 and February 2022. Unable to resolve the ambiguity in the then-pending claim language, Nevro prepared an amendment to the '389 Knudson Application's claims and planned to file a Request for Continued Examination ("RCE"). An applicant may file an RCE with the PTO when seeking further review of a patent application after prosecution is closed.

43. On February 17, 2022, Nevro filed the RCE with the amended claims. In the RCE, Nevro amended the pending claims and further explained that:

> [the claims have been] amended to clarify the nature of the claimed "block," and the positions of the electrodes that produce the block… In addition, Applicant wishes to clarify[] that to "block" – in the context of both the prior art… and the pending claims – is a term of art that means to stop action potentials from propagating in an axon and does not cover a paresthesia-free therapy. Applicant notes that in 2015, the PTAB stated: "Knudson does not disclose a paresthesia-free therapy, either explicitly or inherently"[].

On March 14, 2022, the Examiner allowed Nevro's amended claims.

44. The Agreement expressly provides that Nevro has "control and authority to direct prosecution … including the right to amend such patent applications[.]" The agreement gives Nevro sole discretion in choosing to amend the pending claims in '389 Knudson Application.

45. On May 24, 2022, Defendants revoked Nevro's Power of Attorney for the '389 Knudson Application with no prior notice to Nevro. That same day, Defendants filed an amendment to the claims of the '389 Knudson Application. This amendment puts forth claims in the '389 Knudson Application that Defendants know to be invalid. The language of Defendants' amendment fails to

comply with PTO rules, and if Defendants' claims issue, the resulting patent would be unenforceable due to inequitable conduct being committed by Defendants and their attorneys. Thus, Defendants' actions at the PTO are causing irreparable harm to Nevro.

46. Since submitting the amendment, Defendants have continued to prosecute the '389 Knudson Application, knowingly violating 37 C.F.R. 1.56. Defendants are now taking positions that are wholly inconsistent with past positions taken during prosecution and with the PTO's explicit findings about what the specification of the '389 Knudson Application discloses. On June 30, July 6, and July 7, 2022, Defendants spoke with the Patent Examiner at the PTO on the phone to discuss the status of Defendants' amended claims.[5] On July 7, 2022, Defendants submitted written remarks to the PTO in which they stated that they wished "to clarify or correct multiple inaccurate statements submitted by [Nevro's attorney] on February 17, 2022." The Defendants further stated that "these claims cover at least partially blocking transmission of pain signals… in the spinal cord with or without a sensation of tingling or prickling. To say that the claims do 'not cover a paresthesia-free therapy' as [Nevro's attorney] did on February 17, 2022, is inaccurate." Defendants made that statement despite having full knowledge that the PTO had previously found that "Knudson [the parent of the '389 Application] does not disclose a paresthesia-free therapy, either explicitly or inherently."

47. Defendants actions in prosecuting the '389 Knudson Application are irreparably harming Nevro. Under the Agreement, Nevro has the right to prosecute the '389 Knudson Application, and it has "control and authority" to "amend such patent applications." Defendants do not have the right to amend the claims unilaterally or to make statements to the PTO examiner that affect the scope of the claims. Defendants' actions have deprived Nevro of the opportunity to obtain the claims that Nevro submitted to the PTO on February 17, 2022, and their actions have further clouded the scope of any claims that might ultimately issue.

48. Further, the Agreement gives Nevro the right to enforce any patent that results out of the '389 Knudson Application. If the claims sought by Defendants issue as a patent, the resulting patent will be unenforceable due to Defendants' and their attorneys' inequitable conduct during

[5] IDS and Remarks, submitted July 7, 2022.

prosecution. As a result, the patent's strategic value as part of Nevro's broader patent portfolio will be lost, depriving Nevro of a substantial portion of the value of the patent license, for which it has paid [redacted].

C. Defendants Are Circumventing the Agreement's Mandatory Dispute-Resolution Procedures and Instead Are Unilaterally Prosecuting the '389 Knudson Application

49. Defendants are circumventing the arbitration procedures in the Agreement in an attempt to claim something they did not invent and seek additional royalty payments from Nevro to which they are not entitled.

50. Over the past decade, Nevro and Defendants have conferred about patent prosecution and other matters. Defendants were aware of Nevro's development efforts, that Nevro did not use the "block" therapy, and that the PTO had found that Nevro's "paresthesia-free" therapy was different than the "block" therapy. Defendants also were aware that Nevro paid the "know-how" royalty rate, and they did not object.

51. Defendants' recent assertion that the '389 Knudson Application covers Nevro's "paresthesia-free" therapy surprised Nevro given the parties' long history. The true reasons behind Defendants' sudden change was revealed through multiple communications about this dispute. Leif Nelson, Vice Chair of Mayo Ventures, stated that Mayo's [redacted]. In other words, Mayo experienced [redacted]. Mayo Venture's actions are taken in bad faith, are not fair dealing, and are shocking given the parties' long history and collaboration.

52. Defendants' financial constraints are not a reason for fabricating a disagreement with Nevro about the scope of the claims and specification of the '389 Knudson Application, and are certainly not a basis for violating the parties' Agreement. That Agreement gives Nevro control and authority to direct prosecution, not Defendants. And that Agreement provides that any dispute in the performance of the contract should be resolved through arbitration. The Agreement does not give Defendants a right to revoke Nevro's power of attorney if they disagree with Nevro's prosecution

choices. Instead, if Defendants thought Nevro's prosecution choices were improper or somehow violated the Agreement, Defendants should have pursued their allegations though arbitration, which they did not do. It was improper for Defendants to unilaterally revoke Nevro's power of attorney.

53. Nevro seeks to enjoin Defendants' patent prosecution efforts until an arbitrator can resolve the parties' dispute. Nevro filed a demand for arbitration on July 1, 2022, and that process is proceeding. The Agreement provides that a party may "seek[] equitable relief to protect its rights to the extent that irreparable harm may occur and damages would not be a sufficient remedy." Defendants actions are irreparably harming Nevro because Defendants' and their attorneys' statements to the PTO and in written filings are impacting the scope of any issued claims and Defendants' and their attorneys' actions in seeking invalid claims constitute inequitable conduct.

54. The Agreement provides that either party may petition a court for specific performance of the terms of the arbitration provisions. It further provides that a party securing an order for specific performance is entitled to recover costs and reasonable attorneys' fees in connection with the petition and any related hearings.

CAUSES OF ACTION

COUNT 1: BREACH OF CONTRACT

55. Nevro repeats and incorporates by reference all prior allegations of this Complaint as if fully set forth herein.

56. The Agreement is a valid contract between Flathead, Mayo Foundation, Mayo Ventures, and Nevro.

57. Nevro performed all conditions precedent, to the extent any exist, to demand that Defendants perform their contractual obligations, including their obligations under Section 8.01 of the Agreement.

58. By May 24, 2022, Defendants were in material breach of their contractual obligations under the Agreement as a result of their revocation of Nevro's Power of Attorney with regard to the '389 Knudson Application.

59. Defendants further materially breached their contractual obligations by filing an amendment to the '389 Knudson Application's claims that violates PTO rules and effectively nullifies

Nevro's February 17, 2022 amendment thereto, claims of which were allowed by the U.S. Patent Office.

60. Defendants further materially breached their contractual obligations by filing remarks about the '389 Knudson Application with the PTO asking the PTO to ignore material information and that affect the claim scope.

61. Defendants acted in bad faith through their prosecution of the '389 Knudson Application.

62. Defendants have not cured their material breaches of the Agreement.

63. Nevro has performed or substantially performed all of its material obligations under the Agreement and remains ready, willing, and able to perform such obligations.

64. As a result of Defendants' material breaches of the Agreement, Nevro is no longer able to exercise its right to the control and authority over the '389 Knudson Application's prosecution and maintenance as set forth in the Agreement.

65. If Defendants' amendment is allowed and the claims issue, the resulting patent likely will be unenforceable due to Defendants' and their attorneys' inequitable conduct during prosecution. These actions will deprive Nevro of the patent's strategic value as part of Nevro's broader patent portfolio, as is Nevro's right under the Agreement. Nevro has paid Defendants [redacted] over the years for Nevro's rights under the Agreement.

66. If Nevro is not able to enforce these claims, Nevro will suffer irreparable harm and financial losses, in addition to reputational harm associated with the issuance of unenforceable patents. Nevro is identified in the prosecution record, and Defendants' and their attorneys' inequitable conduct in knowingly seeking invalid claims damages Nevro's reputation.

COUNT 2: BREACH OF CONTRACT BY FAILURE TO ARBITRATE

67. Nevro repeats and incorporates by reference all prior allegations of this Complaint as if fully set forth herein.

68. The Agreement is a valid contract between Flathead, Mayo Foundation, Mayo Ventures, and Nevro.

69. The Agreement contains a clause requiring the parties to submit any dispute concerning

the formation, performance, or termination of the agreement to arbitration.

70. Nevro performed all conditions precedent, to the extent any exist, to demand that Defendants perform their contractual obligations, including their obligations under the dispute resolution provisions of the Agreement.

71. Nevro has notified Defendant about its dispute over the prosecution of the '389 Knudson Application and has filed a demand for arbitration. Defendants unilaterally, and in violation of the Agreement, took control of prosecution of the '389 Knudson Application without allowing for the arbitration process to determine which party shall prosecute the '389 Knudson Application.

72. Defendants have failed to specifically perform under the arbitration provisions of the Agreement.

PRAYER FOR RELIEF

73. Nevro respectfully requests the Court to enter judgment in Nevro's favor on all causes of action alleged in this Complaint.

74. Nevro requests the Court to award Nevro preliminary and permanent injunctive relief pursuant to which Defendants, and each of them, and their employees or representatives, and all persons acting in concert or participating with them are ordered, enjoined, or restrained, directly or indirectly, by any means whatsoever, as follows:

- Defendants shall withdraw the May 24, 2022 Amendment to the '389 Knudson Application;
- Defendants shall cease any other activities related to the prosecution of the '389 Knudson Application without the express written consent of Nevro until the arbitration concludes; and
- Defendants shall immediately return control of the prosecution to Nevro and provide Nevro with the sole power of attorney to prosecute the '389 Knudson Application.

75. Nevro requests the Court to issue an order requiring Defendants to specifically perform under the arbitration provisions of the Agreement and to resolve their dispute over prosecution control of the '389 Knudson Application in arbitration.

76. Nevro requests the Court to award Nevro attorneys' fees and costs.

77. Nevro requests the Court for any other and further relief that this Court deems just and proper.

Dated: July 15, 2022

Respectfully submitted,

SIDLEY AUSTIN LLP

/s/ David L. Anderson
David L. Anderson

Counsel for Plaintiff
NEVRO CORP.